REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-10, 12 and 15-20 are pending. Claims 11 and 13-14 are canceled without prejudice or disclaimer to their later prosecution. Non-elected claims 15-17 were withdrawn from consideration by the Examiner. Applicants note the acknowledgement on page 19 of the Office Action (Paper No. 20) that claims 8-10 are free of prior art.

The amendments are supported by the original disclosure and, thus, no new matter has been added. If the Examiner should disagree, however, she is respectfully requested to point out the challenged limitation with particularity in the next Action so support may be cited in response.

Objections

The description of the drawings (Figs. 3-4) and claim 7 have been corrected as suggested by the Examiner.

Withdrawal of the objections is requested.

35 U.S.C. 101 – Utility

Claims 12-14 were rejected under Section 101 because "use" claims which do not set forth step involved in the process are allegedly informal. Applicants traverse.

Claims 13-14 have been canceled without prejudice or disclaimer. Claim 12 has been amended to include "administration" of the claimed antibody.

Withdrawal of the Section 101 rejection is requested.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with

the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 1-14 and 18-19 were rejected under Section 112, first paragraph. Applicants traverse.

Claims 1-2 and 4-9 are enabled in accordance with the Examiner's statements on pages 3-5 of the Action. The numbering of the amino acid residues in claim 10 has been maintained. Applicants submit that these claims are enabled.

Claim 3 is directed to an antibody which competitively inhibits (i.e., inhibitory antibody) the binding of an antibody specific for CD23. Applicants have added new claim 20 directed to a method of selecting such an inhibitory antibody. Given the CD23-specific antibodies, a method for generating anti-CD23 antibodies, and binding assays which are disclosed by Applicants in their specification, as well as art-known methods for selecting inhibitory antibodies, it would not require undue experimentation to generate antibodies in accordance with claim 3. CD23 antigen would be used to identify other CD23-specific antibodies (i.e., candidate inhibitory antibodies), these other CD23-specific antibodies would be added to a binding assay with C11 antibody (or any of the variant antibodies based on the amino acid sequences of C11 CDRs), and those which competitively inhi-bited binding between C11 and CD23 would be selected as inhibitory antibodies. In particular, a person of skill in the art has no need a priori to know the structure or amino acid sequences of CDRs of such inhibitory antibodies. The skilled artisan would simply screen a library of antibodies for one that "competitively inhibits" binding to CD23. In no way can such a procedure be considered an undue burden.

Claims 12 and 18-19 are directed to treatment or prophylaxis using an anti-CD23 antibody. The Office Action appears to require an "in vivo working example demonstrating that the claimed antibody is effective for treating numerous disorder such as the ones recited in claim 12" (page 10 of the Action). But the statute and case law do not require in vivo working examples to enable these claims because it would not require undue experimentation to show that an anti-CD23 antibody is effective in treatment or prophylaxis. The role of CD23 in the disorders recited in claim 12 has already been established and is shown in the art (see page 4, line 55, et seq. of EP 0788513 and

column 38, line 43, et seq. of U.S. Patent 6,011,138, both of record in the present application). Antibodies of the claimed invention can be used to block function of cell surface or soluble CD23 (e.g., mediation of cell adhesion, regulation of IgE and histamine release, rescue of B cells from apoptosis and regulation of myeloid growth) such that the disorders recited in claim 12 are treated or prevented. Other methods of blocking CD23 function are taught on page 13, lines 10-22, of Applicants' specification. Therefore, if this rejection is maintained, the Patent Office is requested to provide evidence as required by *Marzocchi* that anti-CD23 antibody would not have therapeutic effect when administered to patients afflicted with the recited disorders.

Whether "the antibody may be inactivated before producing an effect" or "other functional properties, known or unknown, may make the antibody unsuitable for in vivo therapeutic use" (page 10 of the Action) is mere speculation by the Patent Office. There is no evidence to show that these problems are probable or likely. Lacking evidence of the likelihood that there are substantial obstacles to using anti-CD23 antibodies, it would require at most routine experimentation to determine whether the claimed antibody is effective in treatment or prophylaxis of any of the recited disorders. Again, evidence is requested to support the Patent Office's speculation.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Claims 1-14 and 18-19 were rejected under Section 112, first paragraph, because it was alleged that they contain "subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention." Applicants traverse because the specification teaches a representative number of species within the claimed genus. Antibody C11 and variant antibodies made from the amino acid sequences of CDRs from C11 (chimeric and humanized antibodies) are sufficient to provide a written description of the pending claims. More antibodies within the scope of the claims would be known to a person of skill in the art using Applicants' disclosure because constant or framework regions for other antibodies are known in the art. Thus, Applicants' variable region combined with an art-known constant region or CDRs grafted to art-known framework regions are also representative of the claimed genus as taught on pages 2-3 of the specification. Many of the antibodies within the scope of claim 1 would satisfy the requirements of claim 3.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention as of the filing date.

35 U.S.C. 112 – Definiteness

Claims 1, 3-14 and 18-19 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse.

The phrase "has sufficient" has been deleted from claim 1 because this limitation is not required for patentability.

Claims 8-9 have been amended to refer to the nucleotide sequences of SEQ ID NOS:1-2 and 17-18 which encode the claimed amino acid sequences, respectively.

Claim 12 has been amended to recite "administration" in the method of treatment or prophylaxis.

Claims 13-14 have been canceled without prejudice or disclaimer.

The Examiner's suggestions for amending the claims to correct informalities are gratefully acknowledged. Adoption of some of his suggestions moots certain rejections.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claims 1-3, 6-7 and 11-14 were rejected under Section 102(b) as allegedly anticipated by Bonnefoy et al. (J. Immunol. 138:2970-2978, 1987). Applicants traverse.

Claims 2, 11 and 13 were rejected under Section 102(e) as allegedly anticipated by Bonnefoy (EP 0788513). Applicants traverse.

Claims 1-3, 6-7 and 11-14 were rejected under Section 102(b) as allegedly anticipated by Plater-Zyberk et al. (Nat. Med. 1:781-785, 1995). Applicants traverse.

Claims 2, 11 and 13 were rejected under Section 102(e) as allegedly anticipated by Reff et al. (U.S. Patent 6,011,138). Applicants traverse.

The claimed invention requires an antibody with particular amino acid sequences in its CDRs (i.e., claims 1-2, 4-10, 12 and 18-19). The antibodies disclosed in the above references do not appear to be C11 antibody or similar to C11. Therefore, the above references do not anticipate antibodies with one or more CDRs derived from C11 antibody in accordance with claims 1-2, 4-10, 12 and 18-19.

Alternatively, the claimed invention requires an inhibitory antibody which competitively binds to CD23 (i.e., claims 3 and 20). With regard to Bonnefoy et al. and Plater-Zyberk et al., there is also no evidence which shows that the antibodies disclosed in these references would competitively inhibit binding by an antibody of claim 1 to CD23 type II molecule expressed on hematopoietic cells. Therefore, these references do not explicitly or inherently anticipate claims 3 and 20.

Withdrawal of the Section 102 rejections is requested because all limitations of the claimed invention are not disclosed by the cited references.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03.

Claims 1, 4-5, 11 and 18-19 were rejected under Section 103(a) as allegedly unpatentable over Bonnefoy et al. or Plater-Zyberk et al. each in view of Newman et al. (U.S. Patent 5,658,570). Applicants traverse.

The failure of Bonnefoy et al. and Plater-Zyberk et al. to disclose an antibody with one or more CDRs derived from the C11 antibody is not remedied by the attempt in the Office Action to modify those disclosures with Newman et al. In particular, none of the cited references teaches or suggests an antibody with the amino acid sequences recited in the claims. Therefore, they would no make obvious the claimed invention.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

Conclusion

Having fully responded to all of the pending objections and rejections contained in the Office Action (Paper No. 20), Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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